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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/807,809	POSSEE ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: copies of scanned drawings

DETAILED ACTION

This office action is in response to an amendment and request for continued examination filed 7/22/2004. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/04 has been entered.

Claims 1-26 and 35-50 have been canceled. Claims 27 and 29 have been amended. Claims 27-34 are pending in this application.

Drawings

Figure 3B, Figure 5 last panel and Figures 7 A-C are objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Figures 3B, Figure 5, last panel, and Figure 7 A-C are photographs of a Northern Blot, Western blot and cell immunofluoresence respectively. The images are dark and no bands or cells are visible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The substitute figures have not improved the resolution of the images. It is noted that the original submission of figure 3 filed 4/18/2001 was clear and the bands in the Northern Blot were visible. Upon resubmission of this figure the image resolution was lost. A copy of the each of the images objected to as well as the original figure 3 accompanies this office action.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague and indefinite in that the metes and bounds of "encoding" a nucleic acid sequence and a gene are unclear. The vector is comprised of nucleic acids, which can encode polypeptides and are comprised of nucleotides. However, the vector does not "encode" other nucleic acid sequences or genes. It would be remedial to recite, "a rescue vector comprising". **This is a new rejection.**

Claim 27 is vague and indefinite in that the metes and bounds of "a nucleic acid sequence, which is capable of restoring replication" are unclear. It is not clear how the nucleic acid sequence "is capable of restoring replication". The sequences can encode a protein that functions in replication, or potentially encode enzymes that restore mutated genes. However, it is not clear how the sequences restore replication. **This is a new rejection.**

Claims 29-30 are vague and indefinite in that the metes and bounds of "functional gene" are unclear. It is unclear what criteria are required to distinguish a "functional" gene. Is it enough that the gene can be transcribed or must it perform additional functions? **This is a new rejection.**

Claims 29-30 are unclear for reciting "a functional gene necessary for restoring the functional gene". It is unclear if this gene is a functional gene required for viral replication or a gene that enzymatically restores the functional gene to its replication competent status. **This rejection is maintained for reasons of record in the office action mailed 4/20/04 and restated above. Upon reconsideration, this rejection has been extended to claim 30.**

Claims 31, 32-34 are vague and indefinite in that the metes and bounds of "functional gene" in claim 29 are unclear. There are two "functional genes" and therefore it is unclear which is referred to in the claims. **This is a new rejection.**

Claims 31-34 are vague and indefinite in that the metes and bounds of "functional gene is" are unclear. The Markush group following this recitation includes wild type genes and "functional fragments or mutations thereof". As the recited genes are wild type genes, it is unclear how the functional gene can be a fragment or mutation. **This is a new rejection.**

Response to Arguments- 35 USC § 112, second paragraph

Applicants traverse the claim rejections under 35 U.S.C 112, first paragraph, on page 7 of the amendment filed 7/22/04. Applicants state "a gene necessary for restoring the functional gene" has been amended to recite "a functional gene" and therefore overcomes the rejection.

Applicant's arguments filed 7/22/04 have been fully considered but they are not persuasive. The claims have not been amended to overcome the rejections under 35 USC 112, second paragraph. Claim 29 is unclear as the nature of the "functional gene" is vague and indefinite. It is unclear how the "functional gene" restores the "functional gene". Does the gene encode a repair gene, a substitute gene, or some other enzyme that can physically repair the non-

functional gene? It appears that the function of the "functional gene" is to replace the non-functional gene, which is supported by the instant specification. If this is the case, it would be remedial to recite "the rescue vector comprises sequences that encode a gene product that replaces the non-functional gene product".

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation that the replication deficient baculovirus is "naked" has been added to claim 27. Applicant has indicated that support for this limitation is found for example on page 6, paragraph 3, page 15 and page 33. These passages teach that the baculovirus replication deficient vector is a DNA molecule based upon the baculovirus genome. The DNA is transfected into the insect cells as part of the recited method. These passages do not teach that the baculovirus vector is "naked" or exactly what "naked" means. The examiner does not find literal support in the originally filed specification for the term "naked". Therefore, the limitation

of "naked" is impermissible NEW MATTER. **This is a new rejection necessitated by applicants' amendment.**

Claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action filed 12/18/02 and 4/20/04 and is restated below.**

Applicants claim a genus of *lef1-12, dnapol, pl43, p35, ie-1, p47, ORF1629 and pp31* genes and functional fragments or mutations thereof.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to a method of generating a replication defective baculovirus vector using a vector lacking a "functional gene" for *lef1-12, dnapol, pl43, p35, ie-1, p47, ORF1629 and pp31*or functional fragments or mutation thereof in combination with a rescue vector comprising sequences encoding the missing gene product. In the instant case, applicants use a replication defective ACMNPV genome 1) deleted of *lef-2,* 2) deleted of *ORF1629, lef-1* and protein kinase 1 or 3) deleted in part of *ORF1629.* Baculovirus comprising

these deletions were used in combination with a rescue vectors comprising a transgene to be cloned and respectively 1) intact *lef-2* (page 20), 2) regions overlapping *lef-2, ORF1629, lef-1* and protein kinase 1 (page 27), and 3) a" transfer vector containing a copy of the lacZ coding region (page 29). Following incubation in insect cells, replication competent baculovirus particles comprising the transgene were produced. There is no disclosure as to functional fragments or mutations of the recited genes apart from the 3' fragment of *ORF1629* that is used in the third of the exemplified methods. Furthermore, the specification does not disclose any of the sequences of the recited genes nor provide a description of the genes such that the structural requirements of the genes can be envisioned. The prior art with the exception of mutational analysis of the *ie-2* gene does not teach structural analysis of the recited genes. Given the large size and diversity of the Baculovirus family , the diversity of the recited genes, the absence of disclosed or art recognized correlations between structure and function and the large number of potential fragments and mutations, it must be considered that any functional fragment or mutation must be empirically determined. By disclosing *lef-2, ORF1629, lef-1* and protein kinase 1, the applicants have not reduced to practice the claimed invention and the relationship between structure and function is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Arguments-35 USC § 112, first paragraph

Applicants traverse the claim rejections under 35 U.S.C 112, first paragraph, on page 5-6 of the amendment filed 7/22/04. Applicants argue that the specification discloses the species-

lef1-12, dnapol, pl43, p35, ie-1, p47, ORF1629 and pp31 and describes required functional characteristics- "necessary for replication". As the structures of the genes are well known in the art and the nature of baculovirus is well characterized, production of functional fragments or mutations is a matter of routine experimentation and empirical determination is not necessary to demonstrate that the applicants had possession of the claimed method.

Applicant's arguments filed 7/22/04 have been fully considered but they are not persuasive. Applicants have recited a large genus of functional fragments and mutations of a diverse set of genes. The basis of the rejection is that the skilled artisan cannot envision which of the fragments or mutations are functional fragments or mutations "necessary for viral replication". The specification lacks any guidance as to the structural requirements of any of the genes that can provide replication function. Therefore, the specification has failed to describe the genes such that the nexus of structure and function is apparent. Given the lack of disclosure as to the structural requirements of the fragments and mutations of the diverse group of recited genes, the skilled artisan cannot envision the detailed structure of the broad class of functional fragments and mutations of a diverse set of genes regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that the sequence is part of the invention and a reference to a potential method for isolating it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (US 6,225,060; see entire document) in view of Patel et al (NAR, Vol 20, pp 97-104; see entire document). **This rejection is maintained for reasons of record in the office action filed 12/18/02 4/24/04 and restated below.**

Applicants claim a method of cloning a gene comprising the steps of providing a naked replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking in the baculovirus vector such as *lef* genes and *ie*. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

The specification does not define "naked" baculovirus. In the amendment filed 7/22/04, applicants argue that the baculovirus is transfected with isolated viral nucleic acid and not infected as with a virus. Hence it is understood that the baculovirus is "naked viral DNA" as opposed to a viral particle.

Clark et al teach use of a baculovirus vector for expression of genetic material. Baculovirus vectors comprising transgenes are generated without utilizing cloning steps (see e.g. column 5, line 1-7). As shown in figure two, the method involves the co-transfection of a DNA from a replication deficient baculovirus, deleted of p35 and orf-1629, and a "rescue" vector comprised of baculovirus p35 and orf-1629 genes as well as the transgene. The vector is "naked" as it is not a viral particle. Following co-transfection into insect cells recombinant baculovirus are selected by screening for replication enablement as a selectable marker (see e.g. column 5, line 1-7 and column 3, line 35-52).

Clark et al do not teach the use of a replication deficient baculovirus vector that can replicate in yeast or bacteria cells as well as insect cells.

Patel et al teaches use of a baculovirus vector that can replicate in Saccharomyces cerevisiae as well as insect cells. A shuttle vector YCbv was generated that could be used to grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (see e.g. page 100, column 1, line 1-8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the replication defective baculovirus vector taught by Clark et al with the yeast or bacterial origins of replication taught by Patel et al because Clark et al teach that it is within the ordinary skill of the art to express replication defective baculovirus in a cell and because Patel teach that it is within the ordinary skill of the art to use yeast or bacteria as host cells for recombinant baculovirus vectors. One would have been motivated to do so in order to receive the expected benefit of reducing time consumption (Patel et al, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Patel et al, page 103, column 2, first paragraph). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 27-34 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitts et al. (Biotechniques, Vol 14 pp 810-817; see entire document) in view of Patel et al.

(NAR, Vol 20 pp 97-104; see entire document). **This rejection is maintained for reasons of record in the office action filed 7/1/03 and is restated below.**

Applicants claim a method of cloning a gene comprising the steps of providing a replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes such as *lef*, *ie* and *ORF1629* are removed from the baculovirus vector. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

The specification does not define "naked" baculovirus. In the amendment filed 7/22/04, applicants argue that the baculovirus is transfected with isolated viral nucleic acid and not infected as with a virus. Hence it is understood that the baculovirus is "naked viral DNA" as opposed to a viral particle.

Kitts et al. teach use of a method for producing recombinant Baculovirus in which an essential gene for replication i.e. *ORF1629* is removed or inactivated from the viral genome (see e.g. figure 1). Cells are transfected with a transfer vector (i.e.BacPAK5 and BacPAK6) that contain *ORF1629* linked to a target gene and a baculovirus vector deleted of *ORF1629*. The vector is "naked" as it is not a viral particle. The baculovirus is rescued following recombination between the genome and BacPAK5 or 6 and thus are replication enabled (see e.g. page 811, column 3, last paragraph). The target gene is then contained in the Baculovirus genome.

Kitts et al do not teach that the replication defective baculovirus vector can be maintained in an intermediate host such as yeast or bacteria.

Patel et al teaches use of a baculovirus vector that can replicate in Saccharomyces cerevisiae as well as insect cells. A shuttle vector YCbv was generated that could be used to

grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (see e.g. page 100, column 1, line 1-8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the replication defective baculovirus vector taught by Clark et al with the yeast or bacterial origin of replication taught by Patel et al because Clark et al teach that it is within the ordinary skill of the art to express replication defective in a cell and because Patel teach that it is within the ordinary skill of the art to use yeast or bacteria as host cells for recombinant vectors. One would have been motivated to do so in order to receive the expected benefit of reducing time consumption (Patel et al, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Patel et al, page 103, column 2, first paragraph). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Arguments- 35 USC § 103

Applicants traverse the claim rejections under 35 U.S.C 103(a) over Clark et al (Clark) in view of Patel et al (Patel) on page 7-9 of the amendment filed 7/22/04. Applicants argue the following. 1) The method of Clark requires use of an apoptosis-deficient host cell line, *Trichoplusia ni* and would not survive in another cell line. 2) The system of Clark has several disadvantages such as it creates a heterogenous population and the vectors replicate at low levels in normal insect cells resulting in contamination of the recombinant particles with parental

baculovirus. Applicants argue that the instant invention attains very high efficiency of recombination and eliminates the need for time-consuming steps to separate the recombinant from parental viruses. 3) Clark and Patel fail to teach, suggest or provide motivation to derive applicants' invention as claimed and to modify the vectors disclosed to enable propagation in yeast or bacterial cells. 4) Patel fails to teach, suggest or provide motivation to use insect cells to generate the recombinant viruses and in fact teaches away from using insect systems asserting that it is the yeast system that allows the rapid generation of the recombinant virus without any background parental virus.

Applicant's arguments filed 7/22/04 have been fully considered but they are not persuasive. While applicants have stated that Clark requires use of an apoptosis-deficient host cell line, *Trichoplusia ni,* support for this statement has not been found. In fact, Clark teaches use of any insect cell and exclusively performs the method in Sf9 cells, which are also used in the instant invention. Secondly, applicants have only presented objective evidence that the vector of Clark et al results in viral particles that are part of a heterogeneous population and replicate at low levels resulting in contamination with parental vectors. No evidence has been provided that would lead a person of skill in the art to conclude that the baculovirus clones generated according to the method of Clark et al are not the same as the baculovirus clones generated by the instant invention. To be of probative value, the objective evidence should be supported by actual proof and not just arguments.

Thirdly, by combining the teachings of Patel with the teachings of Clark the instant invention is rendered obvious as Clark teach recombination in insect host cells. Patel teaches methods for the maintenance of baculovirus genome in yeast cells and Clark methods of

recombination in insect cells using replication deficient baculovirus vectors in combination with rescue vectors. The motivation to combine the references is found in Patel, which specifically addresses the need for a method of maintaining baculovirus that is rapid and efficient and ensures that there is no background of parental virus and eliminates the need for time-consuming plaque assays for the production of baculovirus vectors for cloning. The solution according to Patel et al is the propagation of the virus i.e. in yeast (page 103, column 1), which overcomes many difficulties and time-consuming aspects of existing methods.

Finally, applicants indicate that Patel et al teaches away from using insect cells for recombination by its teachings that homologous recombination is performed in yeast cells and not insect cells. Contrary to this indication, recombination and replication of the baculovirus vectors of Patel et al is performed in yeast and insect cells (see bridging paragraph page 99-100). Recombination by Patel can be performed in yeast cells but this does not indicate that recombination cannot be insect cells.

Applicants traverse the claim rejections under 35 U.S.C 103(a) over Kitts et al in view of Patel et al on page 9-10 of the amendment filed 7/22/04. Applicants argue the following. 1) Kitts et al uses linearized baculovirus DNA in combination with standard transfer vectors which results in the production of only 30-40% of the recombinant viruses in the first round of plaque purification whereas the instant method generates 100% plaques containing recombinant viruses. Furthermore, some viral DNA remains intact as an infectious circular molecule contaminating the sample with parental virus. 2) Kitts et al and Patel fail to teach, suggest or provide motivation to derive applicants' invention as claimed and to modify the vectors disclosed to enable propagation in an intermediate host.

Applicant's arguments filed 7/22/04 have been fully considered but they are not persuasive. First, the instant claims do not limit the method to circular vectors nor is the yield of recombinant vector a recited limitation. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). During prosecution, claims must be interpreted as broadly as their terms reasonably allow. Applicants would like to rely on descriptions of the invention that are not reasonably applied to the claims as written. While applicants state that the viral DNA remains intact, no evidence has been provided such that a person of skill in the art would come to this conclusion. In fact, Kitts teaches that a method of cloning a transgene using a baculovirus vector, BAKPAK6 generates 95% recombinants with no parental contaminants. This provides evidence that the invention of Kitts provides the claimed advantages of the instant invention. Secondly, as argued above in response to arguments against Clark and Patel, it is the combination of references that renders the instant claims non-obvious. The motivation to combine the references is found in Patel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

August 16, 2004

GERRY LEFFERS
PRIMARY EXAMINER